

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

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19th Floor, City Air Tower 159-9, Samseong-dong, Gangnam-gu, Seoul, 135-973 Republic of Korea

PCT

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **14 APRIL 2006 (14.04.2006)**

Applicant's or agent's file reference
PCTA9512-825

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/KR2006/000071

International filing date (day/month/year)

06 JANUARY 2006 (06.01.2006)

Priority date(day/month/year)

06 JANUARY 2005 (06.01.2005)

International Patent Classification (IPC) or both national classification and IPC

C07C 211/29(2006.01)i, A61K 31/135(2006.01)i

Applicant

CJ Corporation et al

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/KR



Korean Intellectual Property Office
920 Dunsan-dong, Seo-gu, Daejeon
302-701, Republic of Korea

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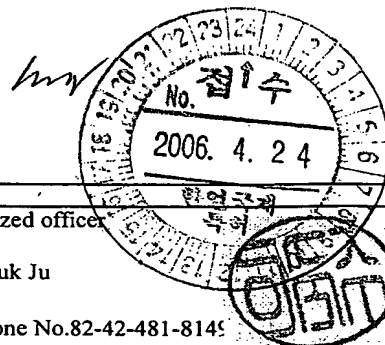
Date of completion of this opinion

13 APRIL 2006 (13.04.2006)

Authorized officer

LEE, Suk Ju

Telephone No. 82-42-481-8145



**WRITTEN OPINION OF THE
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Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ on paper
☐ in electronic form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☐ filed together with the international application in electronic form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 7

because:

☒ the said international application, or the said claims Nos. 7
relate to the following subject matter which does not require an international search (*specify*):

The international Searching Authority is not required to search under PCT Rule 39.1(iv) the subject matter of claim 7 with respect to industrial applicability as it is a method of treating or preventing obesity and related disorders, depression, Parkinson's disease and so on.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for said claims Nos. 7

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13ter.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-6	YES
	Claims	None	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-6	NO
Industrial applicability (IA)	Claims	1-6	YES
	Claims	None	NO

2. Citations and explanations :

Reference is made to the following documents:

D1: WO 98/13034 A1

D2: US 6,331,571 B1

The present invention relates to novel dicarboxylic acid salt of sibutramine, a method of preparing a compound, and a pharmaceutical composition.

Document D1 relates to a pharmaceutical composition for lowering lipid levels in the human body comprising a therapeutically effective amount of a compound of formula I.

Document D2 relates to methods of using and compositions comprising, dopamine, reuptake inhibitors and, in particular, racemic and optically pure metabolites of sibutramine.

I. Novelty and Inventive Step

The subject matter of claims 1~6 differs from the disclosure of D1-D2 mainly in that salt of sibutramine in the chemical formula 1 is dicarboxylic acid salt.

None of the documents D1 and D2 teach or suggest such a dicarboxylic acid salt of sibutramine.

Therefore, the novelty of the subject matter of the present invention can be acknowledged under PCT Article 33(2).

However, document D1 discloses succinates of sibutramine. Documents D1 and D2 disclose tartrates of sibutramine. Difference between dicarboxylic acid salt of the present invention and succinates or tartrates of D1-D2 is carbon number which can be easily chosen or hydroxyl group(OH) which can be simply substituted.

(Continued in Supplemental Box.)

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of :

Box V.

In addition, the present invention is not particularly different from D1-D2 in the pharmaceutical usages and the manufacturing method. Thus the present invention is considered to be easily invented by a person skilled in the art by simply substituting or modifying the well-known compounds. Concerning the effect, there is no remarkable difference over that of D1-D2.

Therefore, the subject matter of claims 1-6 does not satisfy the requirements of PCT Article 33(3).

II. Industrial Applicability

The subject matter of claims 1-6 is considered to be industrially applicable under PCT Article 33(4).

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: